UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Medtronic Inc.,
Securities Litigation

Class Action
Civ. No. 07-4564 (RHK/AJB)
MEMORANDUM OPINION AND ORDER

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INTRODUCTION

Plaintiffs claiming securities fraud are required under the Private Securities Litigation Reform Act ("the Reform Act") to allege the defendants' fraudulent acts and mental state with particularity. 15 U.S.C. § 78u-4(b). These requirements exist because "securities fraud actions . . . if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 127 S. Ct. 2499, 2504 (2007).

Investors in Medtronic, Inc. ("Medtronic"), a Minnesota-based medical device manufacturer, have filed this "class-action" lawsuit alleging corporate and individual malfeasance behind the company's stock-price collapse in 2007. Specifically, Plaintiffs

filed a Consolidated Class Action Complaint[1] accusing Medtronic and three of its high-ranking officers and directors[2] of making material and fraudulent misrepresentations and omissions regarding the efficacy of Medtronic's Sprint Fidelis defibrillator lead.

Defendants have moved to dismiss the Complaint on the ground that it does not comply with the strictures of the Reform Act. After a detailed review, the Court agrees.

BACKGROUND

The following facts are set forth in the Complaint or in documents relied upon therein. Medtronic is a Minnesota corporation with its principal place of business in Minneapolis. (Compl. ¶ 33.) Throughout the time period relevant to this litigation (the "Class Period"),[3] Defendant Arthur D. Collins ("Collins") was a director of Medtronic and Chairman of the Board. (Id. ¶ 34.) Collins was also the Chief Executive Officer ("CEO") of Medtronic from April 2002 to August 23, 2007. (Id.) Defendant William A. Hawkins ("Hawkins") is a director of Medtronic and is the current President and CEO, serving in this capacity since August 23, 2007. (Id. ¶ 35.) Prior to accepting his present position, Hawkins served as President and Chief Operating Officer during the Class Period. (Id.) Defendant Gary L. Ellis ("Ellis") was Senior Vice President and Chief Financial Officer of Medtronic throughout the Class Period. (Id. ¶ 36.)

[1] Hereinafter referred to as the "Complaint."

[2] Medtronic and the individual Defendants are hereinafter referred to collectively as the "Defendants." The individual Defendants are Arthur D. Collins, William A. Hawkins, and Gary L. Ellis. (Compl. ¶¶ 34-36.)

[3] The Class Period in this case is March 21, 2007 through October 15, 2007. (Compl. ¶ 1.) All Plaintiffs purchased Medtronic securities during this time. (Id.)

Medtronic manufactures medical devices, including implantable cardioverter defibrillators ("ICDs"). (Id. ¶ 2.) ICDs are small devices implanted in patients' chests to monitor heart rates and correct heart rhythm disorders. (Id. ¶¶ 2, 46.) Complex wires called "leads" connect the ICD to the patient's heart muscle. (Id. ¶ 4.) If a lead detects that the patient's heart is out of rhythm, the ICD sends an electric shock to the heart muscle through the lead to correct the problem. (Id.) However, if a lead fractures or breaks, it may induce an unnecessary shock, or a shock may not be given when needed. (Id. ¶ 5.)

Defibrillator leads were traditionally thick in diameter to ensure an extended lifespan. (Id. ¶ 49.) However, they were difficult to implant and created a risk of blood clots and tissue growth in the area surrounding the lead. (Id. ¶ 50.) To respond to this problem, Medtronic developed the Sprint Fidelis lead (the "Fidelis lead"), which had a smaller diameter. (Id. ¶ 51.) The Fidelis lead soon became the world's most popular lead and by 2007, Medtronic held a more than 50 percent market share in the defibrillator market. (Id. ¶¶ 3, 54.)

However, problems with the Fidelis lead soon began to surface. In January 2007, two patients at the Minneapolis Heart Institute (the "Heart Institute") suffered unnecessary shocks from their ICDs utilizing the Fidelis lead. (Id. ¶ 58.) An investigation conducted by a physician at the Heart Institute, Dr. Robert G. Hauser, concluded that the shocks were caused by fractures in the leads and that the Fidelis lead was fracturing at a significantly higher rate than other Medtronic leads. (Id. ¶¶ 11-14;

Bongiorno Decl. Ex. D.) The results of this study[4] were communicated to Medtronic on February 15, 2007, prior to its publication in July, 2007. (Compl. ¶ 11; Bongiorno Decl. Ex. D.)

The Hauser Study analyzed the survival rate of the Fidelis lead in comparison to the survival rate of another popular Medtronic lead, the Sprint Quattro. (Compl. ¶¶ 14, 63; Bongiorno Decl. Ex. D.) Of the 583 patients implanted with the Fidelis lead in Dr. Hauser's database, six experienced lead failure. (Bongiorno Decl. Ex. D.) In addition, the Hauser Study searched the Food and Drug Administration ("FDA") Manufacturers and User Facility Device Experience database (the "MAUDE database") for adverse event reports concerning the Fidelis lead, finding "frequent complaints [of] fracture and inappropriate shocks." (Id.; Compl. ¶ 14.) The study also reviewed the returned product analysis done by Medtronic. (Bongiorno Decl. Ex. D.) The Hauser Study noted that it is a "single-center study and may not reflect experiences at other centers. However, the manufacturers' return products data and the MAUDE database findings indicate otherwise." (Bongiorno Decl. Ex. D.)

Dr. Hauser met with Medtronic on February 15, 2007, to discuss his findings. (Compl. ¶ 59.) At this meeting, Warren Watson, a Medtronic vice president and engineer, stated that the study did not present enough evidence to demonstrate a problem with the Fidelis lead. (Id. ¶¶ 60-61.) Watson also expressed his view that the results of the Hauser Study could be the product of physician error. (Id. ¶ 61.)

[4] Hereinafter referred to as the "Hauser Study."

In addition to the Hauser Study, Plaintiffs allege that Defendants were aware that "numerous hospitals and clinics across the country" were "discontinuing implantation of the Fidelis [lead] after encountering fracture problems," and that "at least five patient deaths linked to fractured Fidelis leads" occurred during the Class Period. (Id. ¶¶ 15-16, 85-90.) Upon being confronted with this information regarding the Fidelis lead, Plaintiffs claim that Medtronic undertook a fraudulent campaign to defend their product. (Id. ¶¶ 19-20.) Moreover, in May 2007, Medtronic filed a supplemental premarket approval application with the FDA containing design and manufacturing changes for the Fidelis lead. (Id. ¶¶ 91-92.) According to Plaintiffs, Medtronic filed this application to correct known defects endemic to the Fidelis lead. (Id. ¶ 92.)

On October 15, 2007, Medtronic voluntarily recalled the Fidelis lead. (Id. ¶ 6.) Medtronic stated that its decision to suspend sales of the Fidelis lead stemmed from its review of 30 months of performance data from 25,000 patients implanted with the Fidelis lead indicating that the lead was viable in 97.7 percent of cases, lower than the 99.1 percent viability rate for the Sprint Quattro lead. (Id. ¶¶ 7, 127.) Medtronic noted that while these results were not yet statistically significant, the fracture rate would "become statistically significant over time if the current rates remain[ed] constant." (Id. ¶ 127.)

During the recall announcement, Medtronic noted that pulling the Fidelis lead from the market would cause the company to suffer a revenue loss of $150 to $250 million. (Id. ¶ 7.) Additionally, Medtronic's share price dropped from a close of $56.33 on Friday, October 12, 2007, to a close of $50.00 on Monday, October 15, 2007, an 11.2

percent decline. (Id. ¶ 8.) Medtronic's stock continued to decline to a low of $45.54 on Wednesday, November 7, 2007. (Id. ¶ 9.)

Plaintiffs claim that several statements made by the Defendants during the Class Period (March 21, 2007 through October 15, 2007) were either affirmative misrepresentations or false and misleading in light of omitted information regarding the propensity of the Fidelis lead to fracture. (Id. ¶¶ 97-119.) The challenged statements are contained in: (1) a physician letter; (2) a direct-to-consumer advertising campaign for Medtronic ICDs; (3) Medtronic's website promoting the Fidelis lead to physicians; (4) a May 2007 press release; (5) an Annual Report on Form 10-K; (6) statements made by Medtronic spokesperson Rob Clark; (7) an August 2007 press release; and (8) a Quarterly Report on Form 10-Q. (Id.) Generally speaking, the challenged statements refer to the Fidelis lead's fracture rate, the cause of the Fidelis lead fracturing, the general qualities of the Fidelis lead as durable and reliable, or the ability of the Fidelis lead to produce positive financial results for Medtronic. (Id.) Plaintiffs claim that Defendants were aware that these statements were materially false and misleading when made in light of the undisclosed information regarding the Fidelis lead's fracture rate. (Id. ¶ 148.)

Medtronic now moves to dismiss the Complaint, arguing that Plaintiffs have not pleaded their claims in conformity with the Reform Act.

STANDARD OF DECISION

Although allegations of fraud are generally subject to the heightened pleading requirements of Federal Rule of Civil Procedure 9(b), certain aspects of private securities fraud lawsuits fall under the more demanding pleading requirements of the Reform Act.

Under the Reform Act, a complaint based on material misstatements or omissions must "specify each statement alleged to have been misleading, [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u-4(b)(1)(B). Additionally, a complaint alleging securities fraud must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind" regarding "each act or omission alleged to violate" the securities laws. Id. § 78u-4(b)(2). On a motion to dismiss an action covered by the Reform Act, the Court views factual allegations in the light most favorable to the plaintiff, see Parnes v. Gateway 2000, Inc., 122 F.3d 539, 546 (8th Cir. 1997), and assumes the truth of particularly pleaded allegations, see Fla. State Bd. of Admin. v. Green Tree Fin. Corp., 270 F.3d 645, 666 (8th Cir. 2001). However, the Court disregards "catch-all or blanket assertions." Id. at 660 (internal quotations and citation omitted).

ANALYSIS

Plaintiffs allege that Defendants violated Section 10(b) of the Exchange Act of 1934, 15 U.S.C. § 78j(b) ("Section 10(b)"), Securities and Exchange Commission ("SEC") Rule 10b-5, 17 C.F.R. § 240.10b-5 ("Rule 10b-5"), and Section 20(a) of the Exchange Act of 1934, 15 U.S.C. § 78t ("Section 20(a)"). However, because Rule 10b-5 is coextensive with Section 10(b), see Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 173 (1994); Ernst & Ernst v. Hochfelder, 425 U.S. 185, 195-97 (1976), the Court will analyze the Section 10(b) and Rule 10b-5 claims together.

I. Section 10(b)/Rule 10b-5 claim

Plaintiffs contend that Defendants violated Section 10(b)/Rule 10b-5 by making a series of material and fraudulent misrepresentations and omissions regarding the risks posed by the Fidelis lead. Under Section 10(b), it is unlawful for any person, "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b). Rule 10b-5, in turn, makes it unlawful for any person:

> (a) To employ any device, scheme or artifice to defraud,
> (b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading, or
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To state a violation under Section 10(b)/Rule 10b-5, Plaintiffs must allege: (1) misrepresentations or omissions of material fact; (2) causation; (3) scienter; and (4) economic harm. In re K-tel Int'l, Inc. Sec. Litig., 300 F.3d 881, 888 (8th Cir. 2002). Both falsity and scienter must be alleged with particularity. In re Navarre Corp. Sec. Litig., 299 F.3d 735, 742 (8th Cir. 2002). Defendants argue that the Complaint must be dismissed because it fails to plead the material falsity of the challenged statements or omissions with particularity and because it does not give rise to a strong inference of scienter.

A. Materially false or misleading statements and omissions

The principal allegation in the Complaint is that Defendants failed to disclose material information regarding the risks posed by the Fidelis lead, which rendered a series of statements false and misleading. (Compl. ¶¶ 1-27, 97-119.) In response, Defendants argue that they need not have disclosed such information because it was not statistically significant, and therefore not material; if such omissions are not material, the challenged statements cannot be considered false or misleading. (Def. Mem. at 12-14.) Additionally, the Defendants contend that many of the challenged statements were immaterial "puffery," and therefore not actionable. (Id. at 12.)

An omitted fact is material if there is "a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976). This standard has been "expressly adopt[ed]" for claims arising under Rule 10b-5. Basic Inc. v. Levinson, 485 U.S. 224, 232 (1988). Statements or omissions are not material where they "present or conceal such insignificant data that . . . [they] simply would not matter to a reasonable investor." Parnes, 122 F.3d at 547. Thus, a claim based on an omission of fact faces an "insuperable bar to relief" when alleged omissions are immaterial. In re Amdocs Ltd. Sec. Litig., 390 F.3d 542, 547 (8th Cir. 2004) (internal quotations and citation omitted).

"The trier of fact is uniquely competent to determine materiality, as that inquiry requires delicate assessments of inferences a reasonable investor would draw from a given set of facts." In re Control Data Corp. Sec. Litig., 933 F.2d 616, 621 (8th Cir.

1991) (internal quotations and citations omitted). However, "[w]here a reasonable investor could not have been swayed by an alleged misrepresentation, . . . a court may determine, as a matter of law, that the alleged misrepresentation is immaterial." Parnes, 122 F.3d at 546.

1. Statistical significance and materiality

Defendants contend that the information allegedly possessed by Medtronic regarding the propensity of the Fidelis lead to fracture was not statistically significant, and therefore not material. (Def. Mem. at 11-19.) Medical device and drug manufacturers "need not disclose isolated reports of [harm] suffered by users of their [products] until those reports provide statistically significant evidence that the ill effects may be caused by -- rather than randomly associated with -- use of the [products] and are sufficiently serious and frequent to affect future earnings." In re Carter-Wallace, Inc. Sec. Litig., 150 F.3d 153, 157 (2d Cir. 1998) ("Carter-Wallace I").

In Carter-Wallace I, the Second Circuit held that statements made by a drug manufacturer regarding its drug Felbatol, when the manufacturer knew of several reported Felbatol-linked deaths, were not "materially misleading until [the manufacturer] had information that Felbatol had caused a statistically significant number of . . . deaths and therefore had reason to believe that the commercial viability of Felbatol was threatened." Id. As the Carter-Wallace court stated in a later decision, "until a connection between Felbatol and any illness could be made, we would not expect [the manufacturer] to abandon its product on what, at the time, would have been speculation."

In re Carter-Wallace, Inc. Sec. Litig., 220 F.3d 36, 42 (2d Cir. 2000) ("Carter-Wallace II").

Similarly, in Oran v. Stafford, a securities fraud class action was brought against American Home Products Corp. ("AHP") after two of its drugs were withdrawn from the market. 226 F.3d 275, 279 (3d Cir. 2000). The plaintiffs claimed that "AHP made material misrepresentations and omissions regarding the safety of the drugs while failing to disclose several studies linking the drugs to heart-valve damage." Id. AHP was made aware that a Belgian cardiologist and several Mayo Clinic cardiologists had documented heart-valve abnormalities in several of their patients using these drugs. Id. at 279-80. AHP had "also received hundreds of adverse reaction reports of patients displaying symptoms often associated with heart and lung problems." Id. at 279. AHP did not immediately release these reports, but eventually made an announcement noting a concern that its drugs had "important implications regarding valvular disease," but that no conclusive evidence had established a causal link. Id. at 280.

The Oran plaintiffs contended that statements made by AHP regarding the safety, effectiveness, commercial success, and continued viability of its drugs were materially false and misleading in light of the cardiologists' and adverse reaction reports. Id. at 280-81. The court held that such statements were not materially misleading because "plaintiffs never clearly explain[ed] how the accumulation of additional anecdotal data, short of statistical significance, would have added anything to the disclosures already made." Id. at 284.

Statistical significance, however, is not a bright-line rule because materiality "is a flexible, fact-based determination." In re Bayer AG Sec. Litig., No. 03 Civ. 1546 WHP, 2004 WL 2190357, at *9 (S.D.N.Y. Sept. 30, 2004). In Bayer, the court held that adverse event reports lacking statistical significance, when considered in conjunction with an internal corporate "consensus" that a drug's "potential dangers were putting the brand at risk," were enough to find materiality, id. at *9-10 (internal quotations and citation omitted); adverse event reports, "coupled with other evidence," can demonstrate that "defendants viewed the adverse event reports as sufficiently serious and frequent to affect future earnings." Id. (internal quotations and citation omitted).

Other courts have interpreted Bayer to stand for the principle that omitted "information may become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse . . . events is legitimate and serious enough to threaten . . . sales." In re Elan Corp. Sec. Litig., 543 F. Supp. 2d 187, 210 (S.D.N.Y. 2008); see also In re Bausch & Lomb, Inc. Sec. Litig., No. 06-CV-6294, 2008 WL 4911796, at *20 (W.D.N.Y. Nov. 13, 2008). The Supreme Court has noted that "[a]ny approach that designates a single fact or occurrence as always determinative of an inherently fact-specific finding such as materiality, must necessarily be overinclusive or underinclusive." Basic, 485 U.S. at 236.

2. Puffery

Defendants also argue that many allegedly false and misleading statements are "puffery" and therefore not actionable. (Def. Mem. at 12.) Statements are considered to be puffery when they are "so vague and such obvious hyperbole that no reasonable

investor would rely upon them." Parnes, 122 F.3d at 547. "[S]oft, puffing statements generally lack materiality because the market price of a share is not inflated by vague statements predicting growth. . . . [Moreover,] they are certainly not specific enough to perpetrate a fraud on the market." Id. (quoting Hillson Partners Ltd. P'ship v. Adage, Inc., 42 F.3d 204, 211 (4th Cir. 1994)).

3. The challenged statements

The Complaint alleges that Defendants made several false and misleading statements regarding the risks posed by the Fidelis lead. Each statement is addressed below.

a. The physician letter

Plaintiffs contend that several statements contained in a physician letter sent on March 21, 2007, were materially false and misleading. (Compl. ¶¶ 97-98.) In this letter, Medtronic informed physicians that it had "received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads." (Compl. ¶ 97.) Medtronic stated that it was investigating these reports, and had reviewed them with an Independent Physician Quality Panel, but that the "current overall Sprint Fidelis performance" was "consistent with other leads." (Id.) Furthermore, Medtronic noted that its investigation suggested that "variables within the implant procedure may contribute significantly to these fractures." (Id.) In support of its contention that the Fidelis lead's performance was "in line with other Medtronic leads," Medtronic noted that its System Longevity Study and returned product analysis indicated performance levels of 98.9 percent and

99.86 percent respectively. (Id.) Finally, Medtronic stated that it would communicate additional information as it was learned. (Id. at ¶ 127.)

Plaintiffs contend that this letter was materially false and misleading because it falsely suggested that Fidelis lead fracturing was the result of physician error ("variables within the implant procedure"), and that the lead was performing consistently with other Medtronic leads. (Compl. ¶ 98.) Moreover, Plaintiffs contend that the letter was misleading in that it did not mention: (1) the Hauser Study; (2) the necessity of a recall; (3) the several patient deaths linked to Fidelis lead fracturing; (4) the unreliability of the studies relied upon by Medtronic; (5) the discontinuance by several hospitals and clinics of their purchasing of the Fidelis lead; (6) the fact that there were an "excessive number" of fractures in the Fidelis lead that were "higher" than normally expected;[5] and (7) certain conflicts of interest present within the Independent Physician Quality Panel.[6] (Id.)

[5] These quotations come from statements Medtronic made on October 15, 2007, during two conference calls addressing the Fidelis lead recall. (Compl. ¶¶ 125-28.) During this conference call, a Medtronic representative, Dr. Steinhaus, stated, "As I said earlier, we did have some reports of fractures that were seen to be an excessive number earlier this year and we put out a letter in March." (Id. ¶ 128.) A different representative referred to this statement later in the conference call stating, "as Dr. Steinhaus commented, we saw higher than normal expected rates in the springtime, we looked into those." (Id.) Plaintiffs quote portions of these statements and characterize them as admissions indicating Medtronic's belief during the Class Period that Fidelis lead fracturing was a serious threat to stock prices. (Mem. in Opp'n at 21.) However, when read in context, it becomes clear that such statements refer to the information already discussed in the physician letter. (Compl. ¶ 97.) Therefore, these quotations, plucked out of context, do not demonstrate Medtronic's belief during the Class Period that reports such as the Hauser Study were a serious threat to Medtronic's stock price.

[6] Defendants argue that they had no duty to disclose the alleged conflicts within the Independent Physician Quality Panel. (Def. Mem. at 18-19.) Plaintiffs failed to argue in their brief or at oral argument that any such conflicts were material. Plaintiffs have waived this argument. Nevertheless, the Court finds that such information is not material as Plaintiffs have not pleaded sufficient facts indicating that Panel conflict would influence the reasonable investor. See In re

i. No statistical significance

In large part, Plaintiffs argue that the physician letter was materially false and misleading because it omitted information allegedly known by Defendants regarding the risk of Fidelis lead fracture. However, Plaintiffs do not argue that this information demonstrated to a degree of statistical significance that the Fidelis lead was fracturing at an excessive rate. The lack of statistical significance supports Defendants' contention that this information was not material, and therefore its omission cannot render statements in the physician letter materially false or misleading. See Oran, 226 F.3d at 283-84; Carter-Wallace I, 150 F.3d at 157. Indeed, "[e]ven if scientists suspected that [the Fidelis lead] might cause severe adverse events and Defendants knew of these suspicions, these facts would not have required Defendants to conclude that these effects were real before such a relationship was established using accepted statistical methods and standards of proof." Elan, 543 F. Supp. 2d at 213.

Additionally, the physician letter discloses that Medtronic "received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads," and that Medtronic was "investigating these reports." (Compl. ¶ 97.) There is nothing misleading in these accurate, factual statements. Plaintiffs "never clearly explain how the accumulation of additional anecdotal data, short of statistical significance, would have added anything to the disclosures already made." Oran, 226 F.3d at 284. Accordingly,

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Intrabiotics Pharm., Inc. Sec. Litig., No. C 04-02675 JSW, 2006 WL 2192109, at *9-10 (N.D. Cal. Aug. 1, 2006).

the Court determines that Medtronic's failure to disclose additional statistically insignificant information cannot have been materially misleading in light of the other information disclosed in the physician letter.

ii. No "other indications"

Besides that the allegedly omitted facts lack statistical significance, Plaintiffs assert no "other indications" of materiality demonstrating that the undisclosed information was a sufficiently serious threat to Medtronic's future earnings so as to require disclosure. See Elan, 543 F. Supp. 2d at 210 ("[I]nformation may become material even in the absence of statistically significant evidence in light of other indications that the risk associated with adverse . . . events is legitimate and serious enough to threaten drug sales.").[7] Plaintiffs argue that they allege more than "isolated adverse event reports" – they argue that they also allege five Fidelis lead-related deaths, Medtronic's application to the FDA for approval of design and manufacturing changes,

[7] Plaintiffs rely on In re Amylin Pharmaceuticals, Inc. Securities Litigation and In re Regeneron Pharmaceuticals Securities Litigation to argue that adverse event reports need not be statistically significant to constitute material omissions, even without "other indications" of materiality. Both cases are distinguishable. In Amylin, the court found that while there was no statistically significant data signifying safety issues with a certain prescription drug, statements made by the defendants noting that there were no "clinically important safety issues" and "no major safety concerns" were materially false and misleading in light of clinical trial results associated with "severe adverse events." No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *10 (S.D. Cal. May 1, 2003). In Regeneron, statements informing the public that a newly developed drug "was safe and well tolerated" were held to be materially false and misleading when the drug was efficacious only at toxic dose levels. No. 94 Civ. 1785 (CLB), 1995 WL 228336, at *4-6 (S.D.N.Y. Mar. 10, 1995). Here, by contrast, Medtronic never affirmatively made a false or misleading statement regarding the safety of the Fidelis lead, but instead disclosed explicitly that concerns had come to light regarding Fidelis lead fracturing. Following this disclosure, Medtronic continued to promote a product it considered safe until additional data was accumulated. Medtronic never affirmatively represented any other state of affairs.

the Hauser Study, the discontinuation of Fidelis lead purchasing by several hospitals and clinics, unpublished data indicating decreased Fidelis lead vitality, the strong market reaction to the Fidelis lead recall, and private admissions that Medtronic had a "problem" with the Fidelis lead but was working on a "remedy." (Mem. in Opp'n at 17, 20-22.) Yet, these so-called "other indications," when reviewed separately or in their totality, are insufficient to demonstrate materiality.[8]

First, several of Plaintiffs' "other indications" of materiality were present in Oran and Carter-Wallace I, and found to not be statistically significant and therefore not material. The Oran defendants had received more than one report from cardiologists regarding the health risks posed by certain AHP prescription drugs, as well as hundreds of adverse reaction reports. 226 F.3d at 279-80. In Carter-Wallace I, the defendants had received reports of several deaths related to their drug Felbatol, which were found not to be statistically significant. 150 F.3d at 155-57. Therefore, applying the principles of Oran and Carter-Wallace I, which this Court does, the opinion of Dr. Hauser and the five patient deaths linked to Fidelis lead fracturing are not "other indications" of materiality.

[8] Plaintiffs argued in passing during oral argument, but not in their brief, that Medtronic tried to offer funding to Dr. Hauser to persuade him not to publish his study and that this information is an additional fact demonstrating materiality. This allegation is contained in the products liability Master Consolidated Complaint for Individuals asserted against Medtronic in the Multi-District Litigation, which Plaintiffs attempt to incorporate into their Complaint in this case. (Compl. ¶ 133.) Even if the Court were to consider this allegation, and it will not, such a bald assertion provides no basis to support a materiality finding. The source of this information, according to Plaintiffs, is an anonymous person at the Minneapolis Heart Institute who was privy to communications between Dr. Hauser and Medtronic. Plaintiffs do not explain when or how Medtronic allegedly offered Dr. Hauser funding or how this anonymous person was privy to these alleged communications. There is simply insufficient detail for the Court to consider this naked allegation. Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 782 (8th Cir. 2008).

Second, Medtronic's FDA application for design and manufacturing change approval does not indicate the materiality of the omitted information regarding Fidelis lead fracturing. Plaintiffs plead no facts showing that the FDA application was made in response to a fracturing concern, but merely suspect that such a connection may exist.[9] This vague and conclusory allegation is insufficient to demonstrate materiality. Moreover, an "improvement or upgrade does not mean that the prior [design] was necessarily [flawed]." Abrams v. Baker Hughes Inc., 292 F.3d 424, 433 (5th Cir. 2002); see also In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litig., __ F. Supp. 2d __, No. 08-1905 (RHK/JSM), 2009 WL 35467, at *12 (D. Minn. Jan. 5, 2009) (Kyle, J.).

Third, the allegation that Medtronic had access to information from the CareLink database demonstrating decreased Fidelis lead vitality is inaccurate, as the Complaint itself indicates that the analysis of such data, which involved a lengthy process where 25,000 patients implanted with the lead were analyzed, was not completed until immediately prior to the Fidelis lead recall. (Compl. ¶¶ 127-28.) Therefore, Medtronic did not have access to information indicating decreased Fidelis lead vitality, but instead only had access to raw data, which on its face did not provide substantive information.

Fourth, the fact that a limited number of hospitals and clinics discontinued their purchasing of the Fidelis lead does not indicate that the information regarding Fidelis

[9] Indeed, the Complaint only states that the FDA application sought changes to improve the "def-1 leg strength and handling characteristics" of the Fidelis lead. (Compl. ¶ 92.) Plaintiffs do not explain what this language means.

lead fracturing was material. The Complaint alleges that five hospitals and clinics, in addition to the Heart Institute, suspended purchasing.[10] The suspension of sales by such a limited number of purchasers in a worldwide market does not necessarily indicate that Fidelis lead fracturing was sufficiently serious during the Class Period to affect stock prices. For example, Plaintiffs allege no facts indicating that these select hospitals and clinics purchased a significant number of Fidelis leads.

Fifth, the market's reaction to the Fidelis lead recall does not indicate materiality. It is true that "the fact that a firm's stock price . . . significantly change[s] [upon the release of information] is strong evidence of materiality." No. 84 Employer-Teamster Joint Council Pension Trust Fund v. Am. W. Holding Corp., 320 F.3d 920, 949 (9th Cir. 2003). However, the market's reaction to the Fidelis lead recall is not indicative of how the market would react to the information alleged to have been fraudulently omitted. In fact, the Hauser Study was published during the Class Period in July 2007 (Bongiorno Decl. Ex. D), but neither party notes the impact, if any, this information had on the price of Medtronic securities.[11] Moreover, there is no allegation in the Complaint, beyond unsupported conclusory statements, that Medtronic intended to remove the Fidelis lead from the market during the Class Period. Therefore, the market reaction to the recall is

[10] These hospitals and clinics are: the Children's Memorial Hospital in Chicago, Brigham and Women's Hospital in Boston, New York Hospital and Long Island Jewish Medical Center in New York, and Western Pennsylvania Hospital in Pittsburgh. (Compl. ¶ 86.)

[11] Plaintiffs also argue that materiality is shown by an analyst report discussing recall concerns. (Mem. in Opp'n at 16-17.) However, fears regarding the financial impact of a recall do not address the materiality of statistically insignificant information that does not yet warrant a recall.

irrelevant to the materiality of information allegedly possessed by Medtronic during the Class Period.

Finally, the alleged "admission" indicating that Medtronic had learned of a "problem" with the Fidelis lead and was working on a "remedy," is not additional information indicating materiality. During a second meeting with the doctors from the Heart Institute, Reggie Groves, a Medtronic employee, indicated that she was aware of an issue with the Fidelis lead, but that it did not yet warrant a recall. (Compl. ¶¶ 93-94.) This statement is fully consistent with statements contained in Medtronic's physician letter and does not indicate a "consensus" that such reports "were putting the brand at risk." Bayer, 2004 WL 2190357, at *9-10.[12] In sum, Plaintiffs' alleged "other indications" of materiality, when reviewed separately or in their totality, are insufficient to demonstrate materiality.

iii. Study inadequacies

Plaintiffs' further allege that the physician letter is materially false and misleading because Defendants failed to disclose the inadequacies of the Longevity Study and Returned Product Analysis that were relied upon in the letter. (Compl. ¶¶ 72-73.) The Court does not agree. As the Fifth Circuit stated, "where a company accurately reports the results of a scientific study, it is under no obligation to second-guess the methodology of that study." Nathenson v. Zonagen, Inc., 267 F.3d 400, 420 (5th Cir. 2001) (internal

[12] Plaintiffs asserted during oral argument that Groves' statement regarding a "remedy" referred to Medtronic's FDA application for design and manufacturing changes, therefore supporting the contention that Medtronic submitted the application to address known problems with the Fidelis lead. However, this ambiguous statement, plucked from its context, provides no basis to support the inference that the FDA application was made to address the propensity of the Fidelis lead to fracture.

quotations and citation omitted). Plaintiffs cite no decision holding that the publication of a statistical study is materially false or misleading when purported shortcomings of the study are not disclosed. Moreover, Plaintiffs do not assert that the results of these studies were fabricated or otherwise disbelieved by Defendants when the physician letter was published. Therefore, the inadequacy of the studies relied upon by Defendants "is insufficient to allege fraud." In re Sepracor, Inc. Sec. Litig., 308 F. Supp. 2d 20, 36 (D. Mass. 2004).

iv. "Blaming" Fidelis lead fracturing on physician error

Plaintiffs argue that the statement in the physician letter "blaming reported problems on physician error" was materially false and misleading on its face without regard to any omitted information. (Mem. in Opp'n at 1, 24.) Specifically, the letter stated that "variables within the implant procedure may contribute significantly to these fractures." (Compl. ¶ 97.) To support their argument, Plaintiffs rely on Mississippi Public Employees' Retirement System v. Boston Scientific Corp., 523 F.3d 75 (1st Cir. 2008). In that case, the defendants stated that problems associated with their medical device were connected with doctor unfamiliarity, but later admitted that they initiated a manufacturing change to address a problem with the device itself. Id. at 87. The court held that a jury could find that assertions blaming product failures on doctor unfamiliarity were "misleading unless accompanied by disclosure of the manufacturing change." Id. However, Mississippi Public is distinguishable because Plaintiffs here have pleaded no facts indicating that Medtronic sought design changes to address what it believed was a

defect in the Fidelis lead. Simply put, nothing in the Complaint suggests that Medtronic's investigation did not actually indicate that the single-center reports of Fidelis lead fracturing may be attributable to implant procedures.[13]

b. All other challenged statements

The analysis above regarding the material falsity of statements contained in the physician letter applies with equal force to all other challenged statements contained in Medtronic's direct-to-consumer advertising campaign, website, press releases, SEC filings, and spokesperson statements. The information Plaintiffs claim was fraudulently omitted from these statements was not material as it was not statistically significant. See Oran, 226 F.3d at 283-84; Carter-Wallace I, 150 F.3d at 157. Moreover, there is nothing to suggest that such undisclosed information constituted a sufficiently serious threat to Medtronic's stock price as to render such information material. See Bayer, 2004 WL 2190357, at *9-10. Accordingly, no challenged statement is actionable. However, there are additional reasons why the remaining statements are not materially false and misleading, as described below.

i. A direct-to-consumer advertising campaign

In January 2007, Medtronic began a direct-to-consumer advertising campaign promoting its defibrillators, 90 percent of which used the Fidelis lead. (Compl. ¶¶ 99-100.) The advertisements stated in part that Medtronic defibrillators would provide

[13] Indeed, if Medtronic's own statistical data indicated that Fidelis performance was in line with other Medtronic leads, and Medtronic had only received a limited number of reports of fracturing from implanting physicians, a reasonable explanation for this contradictory information may be the improper implantation procedures of the reporting physicians.

"10,000 more kisses" and other similar statements suggesting that a defibrillator would help prolong the lifespan of persons suffering from heart conditions. (Id. ¶¶ 99, 104-05.)

Such statements are not actionable -- they are "promotional phrase[s] used to champion the [Fidelis lead] but [are] devoid of any substantive information." Parnes, 122 F.3d at 547 (quoting Searls v. Glasser, 64 F.3d 1061, 1066 (7th Cir. 1995)). Indeed, their "lack of specificity precludes [the ads] from being deemed material; [the ads contain] no useful information upon which a reasonable investor would base a decision to invest." Id. (quoting Searls, 64 F.3d at 1066).

ii. Information on Medtronic's website

Throughout the Class Period, Medtronic published information about the Fidelis lead on its website to promote it to physicians. (Compl. ¶ 107.) The website stated that the Fidelis lead has "Outstanding Electrical Performance," is "durable and reliable," and is designed to "resist fracture." (Id.) Plaintiffs contend that these statements are materially false and misleading because the Fidelis lead was neither "durable or reliable" nor fracture resistant. (Id. ¶ 108.)

No reasonable investor would rely upon these promotional phrases in making investment decisions. See Parnes, 122 F.3d at 547. Moreover, during the Class Period, physicians visiting the Medtronic website would presumably have received the above-referenced physician letter disclosing that Medtronic had "received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates" with the Fidelis lead. (Compl. ¶ 97.) Therefore, these statements were not false in light of disclosures already made.

iii. Press releases, Annual Report on Form 10-K, and Quarterly Report on Form 10-Q

On May 22, 2007, a press release announced "positive financial results" for Medtronic in the fourth quarter and fiscal year, and specifically noted earnings growth and discussed expansion in product lines utilizing the Fidelis lead. (Id. ¶ 109.) In its subsequent Annual Report on Form 10-K, Medtronic reconfirmed the financial results reported in this press release. (Id. ¶ 110.) In this report, Medtronic further noted that its financial growth was "aided by continued strong performance of [the] Sprint Fidelis leads," which had "strong market acceptance." (Id.)

On August 21, 2007, another Medtronic press release announced Medtronic's first quarter financial results, touting the strong performance of Medtronic products. (Id. ¶ 116.) This release also stated that Medtronic is "well positioned in some of the most attractive worldwide markets, and [has a] top flight leadership team that will help take Medtronic to the next level." (Id.) In its subsequent Quarterly Report on Form 10-Q, Medtronic reaffirmed the financial results of this press release, predicting that Medtronic's future financial performance would be strong. (Id. ¶ 117.) The Quarterly Report also predicted future growth in defibrillator demand. (Id. ¶ 118.) Plaintiffs contend that all these press releases and reports were materially false and misleading because positive statements regarding Medtronic's financial status were lacking in any reasonable basis given the undisclosed information regarding Fidelis lead fracturing. (Id. ¶¶ 112, 119.)

Statements in the press releases and reports regarding the "strong performance" and "market acceptance" of the Fidelis lead and Medtronic's belief in its future economic growth were not false and misleading. Plaintiffs do not allege that Medtronic's sales, including sales of the Fidelis lead, were not producing economic success during the Class Period. Moreover, Plaintiffs do not allege that the few hospitals and clinics that discontinued their purchasing of the Fidelis lead harmed the lead's overall market performance. Therefore, these statements are accurate historical data and not actionable. In re Sofamor Danek Group, Inc., 123 F.3d 394, 401 (6th Cir. 1997).

In addition, the statement that Medtronic is "well positioned in some of the most attractive worldwide markets, and [has a] top flight leadership team that will help take Medtronic to the next level" is no more than a "promotional phrase used to champion the company [that] is devoid of any substantive information." Parnes, 122 F.3d at 547 (internal quotations and citation omitted). "[S]tatements containing simple economic projections, expressions of optimism, and other puffery are insufficient" to establish securities fraud. Novak v. Kasaks, 216 F.3d 300, 315 (2d Cir. 2000).

iv. Statements made by Medtronic spokesperson Rob Clark

On July 30, 2007, an article in the Minneapolis Star Tribune newspaper reported the findings of the Hauser Study, quoting statements made by Medtronic spokesperson Rob Clark. (Compl. ¶¶ 113-14.) Clark stated that the study "must be taken in context" as it is a single-center study and cannot "represent the total performance experience of the Fidelis lead." (Id. ¶ 114.) Plaintiffs contend that this statement is materially false and

misleading because it fails to disclose information indicating that the Fidelis lead was prone to fracturing. (Id. ¶ 115.) However, Clark's statement is an accurate factual statement. Indeed, the Hauser Study itself states that it "is a single-center study and may not reflect the experiences at other centers." (Bongiorno Decl. Ex. D.)

In sum, the statements made by Medtronic during the Class Period did not "create an impression of a state of affairs" regarding the Fidelis lead that materially differed from the one that actually existed. Brody v. Transitional Hosps. Corp., 280 F.3d 997, 1006 (9th Cir. 2002). Therefore, Plaintiffs have failed to plead a materially false or misleading statement with particularity.[14]

B. Scienter

Defendants also argue that the Complaint must be dismissed because it does not create a "strong inference" of scienter. (Def. Mem. at 20-36.) The Court agrees. While not expressly required by the language of Section 10(b)/ Rule 10b-5, a defendant's mental state is nonetheless "an acknowledged essential element of a § 10(b) or Rule 10b-5 claim." Alpern v. UtiliCorp United, Inc., 84 F.3d 1525, 1534 (8th Cir. 1996). The Reform Act requires a complaint to "state with particularity facts giving rise to a strong

[14] In their Motion papers, the parties vigorously dispute the continued viability of the "Group Pleading Doctrine" since the passage of the Reform Act. (Def. Mem. at 37; Mem. in Opp'n at 34-35.) The Eighth Circuit has yet to address this issue. See In re Hutchinson Tech., Inc. Sec. Litig., 536 F.3d 952, 961 n.6 (8th Cir. 2008). The Group Pleading Doctrine presumes that "statements in prospectuses, registration statements, annual reports, press releases, or other group-published information, are the collective work of those individuals with direct involvement in the everyday business of the company." In re Oxford Health Plans, Inc., 187 F.R.D. 133, 142 (S.D.N.Y. 1999) (internal quotations and citation omitted). However, because the Court finds that no challenged statement is materially false or misleading, the Court need not address whether the challenged statements can be imputed to the individual Defendants.

inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2).

In deciding whether a strong inference of scienter has been adequately pleaded, a court must determine "whether *all* the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." Tellabs, 127 S. Ct. at 2502. On a motion to dismiss, while "all inferences must be drawn in plaintiffs' favor, inferences of scienter do not survive if they are merely reasonable. . . . Rather, inferences of scienter survive a motion to dismiss only if they are both reasonable and 'strong.'" Green Tree, 270 F.3d at 660 (internal quotations and citation omitted). Therefore, a court "must consider, not only inferences urged by the plaintiff, . . . but also competing inferences rationally drawn from the facts alleged." Tellabs, 127 S. Ct. at 2504. The outcome of this comparison must indicate that the "inference of scienter [is] more than merely plausible or reasonable -- it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." Id. at 2504-05. Additionally, "to proceed beyond the pleading stage, [a plaintiff] must allege facts sufficiently demonstrating *each defendant's* state of mind regarding his or her alleged violations." Phillips v. Scientific-Atlanta, Inc., 374 F.3d 1015, 1018 (11th Cir. 2004) (emphasis added).

A strong inference of scienter may be established when the defendants "(1) benefited in a concrete and personal way from the purported fraud, (2) engaged in deliberately illegal behavior, (3) knew facts or had access to information suggesting that their public statements were not accurate, or (4) failed to check information they had a

duty to monitor." Kushner v. Beverly Enters., Inc., 317 F.3d 820, 827 (8th Cir. 2003). Plaintiffs contend that scienter can be strongly inferred in this case because Defendants knew facts, or had access to facts, suggesting that the Fidelis lead posed a significant fracture risk. (Mem. in Opp'n at 36-48.) Moreover, Plaintiffs contend that a strong inference of scienter has been alleged in this case because evidence of insider trading indicates that the individual Defendants derived personal benefit from their fraudulent statements. (Id. at 48-49.)

1. Knowledge of facts indicating that public statements were inaccurate

"One of the classic fact patterns giving rise to a strong inference of scienter is that defendants published statements when they knew facts or had access to information suggesting that their public statements were materially inaccurate." Green Tree, 270 F.3d at 665. Plaintiffs allege that Defendants knew of information regarding the fracture rate of the Fidelis lead at the time the allegedly fraudulent statements were made, that knowledge of this information creates a strong inference of scienter, and that such knowledge can be imputed to Medtronic. (Mem. in Opp'n at 36-48.)

a. The individual Defendants

Plaintiffs claim that the individual Defendants were aware that their statements were materially false and misleading because they were aware of information such as the Hauser Study, the unreliability of Medtronic's internal statistics, the decision of several

hospitals and clinics to suspend their purchasing of the Fidelis lead,[15] the FDA application for design and manufacturing changes, and the five patient deaths linked to Fidelis lead fracturing.[16] (Mem. in Opp'n at 36-37.)

"Without allegations of particular facts demonstrating how the defendants knew" of the alleged information indicating the propensity of the Fidelis lead to fracture, fraudulent intent cannot be shown. Kushner, 317 F.3d at 827. This is because "[c]orporate officials need not be clairvoyant; they are only responsible for revealing those material facts reasonabl[y] available to them." Navarre, 299 F.3d at 743 (internal quotations and citations omitted). In this case, Plaintiffs have not made a sufficient showing of such knowledge, and accordingly the individual Defendants' scienter has not been established.

First, Plaintiffs allege that the individual Defendants must have been aware of information indicating that the Fidelis lead was prone to excessive fracturing because of their senior-level positions at Medtronic. (Mem. in Opp'n at 42-43.) However, "[a]

[15] Plaintiffs request that the Court take judicial notice of an article published by Minnesota Public Radio, in which Medtronic spokesperson Rob Clark is quoted as stating that Medtronic had received reports that some medical centers had suspended their purchasing of the Fidelis lead. (Strauss Decl. Ex. E.) This article is offered to establish the Defendants' knowledge of such discontinuances, but the Defendants dispute this knowledge. (Def. Mem. at 28-29.) Because disputed facts are not the proper subject of judicial notice, the Court will not consider statements in this article. See Kushner, 317 F.3d at 830 (quoting Fed. R. Evid. 201(b)).

[16] Plaintiffs also claim that the Complaint establishes a strong inference of scienter because "Defendants admittedly knew about the 'higher than normal expected' and 'excessive' rates of fracturing detected by springtime." (Mem. in Opp'n at 36.) As noted above, Plaintiffs take these statements, made during a conference call on the day the Fidelis lead was recalled, out of context. (Compl. ¶¶ 125-28.) When the record of the conference call is read, it becomes clear that the speakers were referring to the adverse reports already disclosed in the physician letter, and not some additional information or knowledge that the Fidelis lead was prone to excessive fracturing.

pleading of scienter may not rest on the inference that defendants must have been aware of [information] based on their positions within the company." Abrams, 292 F.3d at 432. Indeed, "respective positions within the company prove nothing about fraud or knowledge thereof but rather are exactly the type of generalized allegations the court must disregard under the [Reform Act]." In re Patterson, Inc. Sec. Litig., 479 F. Supp. 2d 1014, 1032-33 (D. Minn. 2007) (Doty, J.) (internal quotations and citation omitted).

Plaintiffs further allege that Defendants must have been aware of information regarding the propensity of the Fidelis lead to fracture because the Fidelis lead was a very important product for Medtronic. (Mem. in Opp'n at 42-43.) A court may infer "that individuals in top management of a corporation are aware of matters central to that business's operation." In re McLeodUSA Inc. Sec. Litig., No. C02-001-MWB, 2004 WL 1070570, at *6 (N.D. Iowa Mar. 31, 2004). However, Plaintiffs have not sufficiently alleged that the Fidelis lead was central to Medtronic's business. While Plaintiffs argue that the Fidelis lead was generating one billion dollars in revenue and its recall had a significant negative impact on Medtronic's stock price (Mem. in Opp'n at 42 n.27), Defendants note that the Fidelis lead was one of many Medtronic products, with its recall impacting only two percent of revenues. (Reply Mem. at 13 (citing Compl. ¶¶ 2, 109, 127).) Therefore, the Fidelis lead was not so important to Medtronic's continued success to support the inference that the individual Defendants must have known all information regarding it.

Plaintiffs also argue that a strong inference of scienter is established for the individual Defendants because they had access to information regarding the Fidelis lead

through their monitoring of sales and performance data. (Mem. in Opp'n at 37, 45-46.) Plaintiffs point to the statement in the physician letter that Medtronic was closely monitoring the Fidelis lead and was in close contact with physicians. (Id. at 45.) However, Plaintiffs' argument fails because an allegation of data monitoring is not sufficiently specific to support a strong inference of scienter. See In re Apple Computer, Inc. Sec. Litig., 243 F. Supp. 2d 1012, 1026 (N.D. Cal. 2002) (noting that "general allegations about a 'hands-on' management style" and "access to data is insufficient to support a securities claim.") Indeed, in this case, there is no allegation in the Complaint that any individual Defendant actually studied the sales and performance data of the Fidelis lead. Moreover, Plaintiffs fail to explain why the simple review of sales and performance data would convey to the reader that the Fidelis lead was fracturing at a significant rate or posing a serious threat to Medtronic stock prices. Thus, such a broad and unsubstantiated allegation fails to establish a strong inference of scienter.

Plaintiffs again rely upon Mississippi Public to support a finding of a strong inference of scienter for the individual Defendants. However, Mississippi Public is easily distinguished as that court relied heavily upon the "company's own statements" indicating that it implemented manufacturing changes to address a known defect in its product while publicly maintaining that the product was not defective. 523 F.3d at 87-88. No similar allegation, beyond mere conclusory statements, is made here.[17]

[17] Plaintiffs cite no facts indicating that Medtronic applied to the FDA for design and manufacturing changes for the purpose of addressing Fidelis lead fracturing.

Finally, Plaintiffs allege that Defendants admitted their knowledge of excessive Fidelis lead fracturing when Medtronic employee Reggie Groves stated that Medtronic had "identified a problem and was working on a possible remedy." (Mem. in Opp'n at 37.) However, Plaintiffs allege no facts indicating that the sentiment of Reggie Groves was communicated to the individual Defendants or had pervaded Medtronic. Additionally, this quotation is vague, ambiguous, and plucked from its context. Such "ambiguities count against inferring scienter." Tellabs, 127 S. Ct. at 2511.

The Complaint in this case is "replete with blanket assertions of knowledge that do not particularly state facts upon which such knowledge was based or increase the reasonableness or strength of an inference that any defendant acted with an intent to defraud the market." Patterson, 479 F. Supp. 2d at 1032. Therefore, a strong inference of scienter has not been established for any of the three individual Defendants based on knowledge of information contradicting public statements.[18]

b. Medtronic

Plaintiffs argue that a strong inference of scienter can be imputed to Medtronic without adequately pleading scienter against any individual Defendant. (Mem. in Opp'n

[18] Plaintiffs also rely on several allegations contained in the Master Consolidated Complaint for Individuals asserted against Medtronic in the Multi-District Litigation. (Mem. in Opp'n at 37-38.) Such allegations include that Medtronic employees attempted to offer funding to Dr. Hauser in order to delay the publishing of the Hauser Study, that Medtronic misrepresented to the FDA that the Fidelis design was "based on" and "substantially similar to" previously approved leads, that members of Medtronic's advisory committee noted that data cited in the physician letter was inadequate to support the letter's conclusions, and that Medtronic delayed the disclosure of 120 adverse event reports. (Id.) In their Complaint, Plaintiffs attempt to incorporate these allegations. (Compl. ¶ 133.) Even were the Court to consider such allegations, they suffer from the same flaw as all other scienter allegations already discussed: Plaintiffs do not sufficiently plead the individual Defendants' knowledge of such alleged actions.

at 40-42.) Specifically, Plaintiffs request that this Court adopt the "collective corporate scienter" doctrine, which allows a plaintiff to demonstrate corporate scienter "through the sum of its employees' 'activities and knowledge.'" In re WorldCom, Inc. Sec. Litig., 352 F. Supp. 2d 472, 497-500 (S.D.N.Y. 2005); see also United States. v. Bank of New England, N.A., 821 F.2d 844, 856 (1st Cir. 1987).

In contrast, the Fifth Circuit has held that to determine corporate scienter, a court must look to the scienter of individual corporate officials. See Southland Sec. Corp. v. INSpire Ins. Solutions, Inc., 365 F.3d 353, 366 (5th Cir. 2004). The scienter of individual corporate officials is important because when subjective state of mind is an element of a cause of action, such as fraud, the general common-law rule requires such a state of mind to actually exist in an individual. Id. Therefore, a corporation should be "deemed to have the requisite scienter for fraud only if the individual corporate officer making the statement has the requisite level of scienter." Id. (internal quotations and citation omitted).

While the Eighth Circuit has not directly addressed the issue of "collective scienter," it has done so implicitly. In Kushner, after determining that the plaintiffs had not established a strong inference of scienter for any individual corporate employee, the court dismissed the complaint without mentioning or addressing the scienter of the corporate defendant. 317 F.3d at 827-30. This result is consistent with Southland. Therefore, the Court will not apply the "collective scienter" doctrine, requiring instead that the Plaintiffs establish corporate scienter by adequately alleging the scienter of individual corporate officers. Because Plaintiffs have not adequately pleaded scienter

against any individual Defendant or non-defendant Medtronic employee, corporate scienter cannot be established.[19]

2. Competing inferences

Even if Defendants were aware of information indicating that the Fidelis lead was prone to fracture during the Class Period, Defendants argue that the competing inference of Medtronic's good faith is "the far more cogent and compelling inference on the record," and therefore, Plaintiffs cannot establish a strong inference of scienter. (Def. Mem. at 27.) Specifically, Defendants claim that during the Class Period, Medtronic "acted in good faith by waiting to make any decision until it had analyzed a much larger body of data." (Id.) Plaintiffs do not contest that Medtronic conducted an extensive statistical study of over 25,000 patients implanted with the Fidelis lead during the Class Period, culminating with findings that led to the recall of the Fidelis lead. Thus, a strong inference exists that Medtronic acted in good faith in addressing the reports of Fidelis lead fracturing. See Higginbotham v. Baxter Int'l, Inc., 495 F.3d 753, 760-61 (7th Cir. 2007) ("Prudent managers conduct inquiries rather than jump the gun with half-formed

[19] In Makor Issues & Rights, Ltd. v. Tellabs Inc., the Seventh Circuit noted that "it is possible to draw a strong inference of corporate scienter without being able to name the individuals who concocted and disseminated the fraud." 513 F.3d 702, 710 (7th Cir. 2008). The court gave the following example: "Suppose General Motors announced that it had sold one million SUVs in 2006, and the actual number was zero. There would be a strong inference of corporate scienter, since so dramatic an announcement would have been approved by corporate officials sufficiently knowledgeable about the company to know that the announcement was false." Id. Therefore, the Seventh Circuit has indicated that some fraudulent statements may be so flagrant as to support an inference of corporate scienter even when the knowledge of individual officers and directors cannot be determined. The Ninth and Second Circuits agree with this reasoning. See Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 195 (2d Cir. 2008); Glazer Capital Mgmt. v. Magistri, 549 F.3d 736, 744-45 (9th Cir. 2008). However, the case at bar presents no similarly obvious or flagrant fraud.

stories as soon as a problem comes to their attention. . . . Taking the time necessary to get things right is both proper and lawful.").

Moreover, even if the individual Defendants were aware of the FDA application to implement design and manufacturing changes in the Fidelis lead, such an application does not necessarily imply knowledge that the Fidelis lead was prone to excessive fracturing. An "improvement or upgrade does not mean that the prior [design] was necessarily [flawed]. A perfectly reasonable explanation for implementing [design changes is] to improve [the product]." Abrams, 292 F.3d at 433. Therefore, Defendants have presented a strong competing inference of good faith, cutting against any inference of scienter.

3. Concrete and personal benefit to Defendants

A second way in which a strong inference of scienter can be established is by demonstrating that a defendant derived concrete and personal benefits from the alleged fraud. Kushner, 317 F.3d at 827. "[M]otive and opportunity are generally relevant to a fraud case, and a showing of unusual or heightened motive will often form an important part of a complaint that meets the Reform Act standard." Green Tree, 270 F.3d at 660. This is because strong motive is a "reason to believe the defendant's misrepresentation was knowing or reckless." Id.

Plaintiffs argue that Defendants had the motive to commit securities fraud because of their desire to maintain Medtronic's 50 percent "market-share in the lucrative defibrillator market." (Mem. in Opp'n at 36.) However, motives generally held by all corporate officers and directors are insufficient to establish a strong inference of scienter.

Green Tree, 270 F.3d at 664. All corporate officers and directors want their corporations to be financially successful. Therefore, this motive does not support a strong inference of scienter.

Plaintiffs also argue that the individual Defendants' insider stock sales demonstrate a motive to commit securities fraud, and therefore create a strong inference of scienter. (Mem. in Opp'n at 48-49.) However, insider sales "are not inherently suspicious; they become so only when the level of trading is dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from the undisclosed information." Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 783 (8th Cir. 2008) (internal quotations and citations omitted). Thus, "insider trades have to be 'unusual,' either in the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved, before they will give rise to the required inference of scienter." Green Tree, 270 F.3d at 659.

In this case, insider stock sales by the individual Defendants during the Class Period were not unusual or suspicious.[20] "When evaluating stock sales, . . . the proportion of shares actually sold by an insider to the volume of shares he could have sold is probative of whether the sale was unusual or suspicious." In re Silicon Graphics Inc. Sec. Litig., 183 F.3d 970, 986 (9th Cir. 1999). Defendants note that during the Class Period, Defendant Hawkins sold 1% of his stock holdings, Defendant Ellis sold .2% of

[20] In their Complaint, Plaintiffs reference the stock sales of several non-Defendant insiders. (Compl. ¶¶ 168-70.) In their brief and at oral argument, however, Plaintiffs do not allege that such sales create a strong inference of scienter. Therefore, the Court need not address the stock sales of any non-Defendant.

his holdings, and Defendant Collins sold 14% of his holdings.[21] (Def. Mem. at 33-34.) These percentages, standing alone, are insufficient to establish a strong inference of scienter. See Navarre, 299 F.3d at 747 (noting that sales of ten percent and thirty-two percent of an insider's stock holdings, standing alone, is insufficient to establish a strong inference of scienter).

Instead of relying on such percentages, Plaintiffs claim that Defendants' stock sales were unusual and suspicious because of the sale dates and amount of stock sold during the Class Period. (Mem. in Opp'n at 48-49.) However, the amount of stock sold by Defendants during the Class Period is insufficient to establish a strong inference of scienter. While Plaintiffs claim that "Collins' Class Period sales were more than seven times -- and Hawkins', more than four times -- their respective sales during the prior fourteen-month period" (Mem. in Opp'n at 48), Defendants note that the trading of both Hawkins and Ellis resulted in increased stock holdings during the Class Period. (Def. Mem. at 33.) [22] When insiders increase their stock holdings during the Class Period, it weakens the allegation of suspicious insider trading. See Possis, 519 F.3d at 783. Moreover, a strong competing inference exists that Collins' stock sales during the Class Period were not unusual or suspicious, as he was exercising stock options soon to expire, utilizing a majority of the profits derived from the stock sales to pay taxes incurred

[21] The Defendants' trading history is "documented in public filings required to be filed with the SEC, which [can be] considered on a motion to dismiss." Green Tree, 270 F.3d at 663. Plaintiffs do not challenge these percentages.

[22] Notably, Plaintiffs' brief does not discuss the insider trading of Ellis.

through the exercise of the options. (Def. Mem. at 35.)[23] Stock sales done in conjunction with the exercise of an option or to pay taxes are not suspicious. See Campbell v. Lexmark Int'l Inc., 234 F. Supp. 2d 680, 687 (E.D. Ky. 2002); Ressler v. Liz Claiborne, Inc., 75 F. Supp. 2d 43, 59-60 (E.D.N.Y. 1998).

Plaintiffs claim that the timing of Collins' stock sales, in particular, is suspicious. They note that "Collins sold 338,896 shares on July 2, 2007 -- five days after the June 25, 2007, issuance of Medtronic's 2007 Form 10-K." (Mem. in Opp'n at 49.) Moreover, Plaintiffs note that Collins "also sold 38,000 shares on August 23, 2007, two days after the August 21, 2007 press release" and "sold 69,566 shares on September 17 and 18, 2007, a week after the September 5, 2007, issuance of Medtronic's false first quarter Form 10-Q and weeks before the October 15, 2007, corrective disclosure." (Id.)

Plaintiffs are correct that the suspicious timing of stock sales can create an inference of scienter. Silicon, 183 F.3d at 987. However, the timing of Collins' stock sales is explained largely by the expiration date of the options he exercised during the Class Period. Moreover, even if the timing of Collins' stock sales was considered by the Court to be suspicious, such timing is insufficient to establish a strong inference of scienter in the absence of any other information indicating unusual insider trading.

4. Conclusion: Plaintiffs fail to allege a strong inference of scienter

All of Plaintiffs' factual allegations, whether considered individually or in their totality, do not establish a strong inference of scienter. Defendants' senior positions at

[23] Plaintiffs do not contest this fact.

Medtronic, the importance of the Fidelis lead to Medtronic's business, Defendants' access to information databases, Defendants' desire to maintain a 50 percent market share in the defibrillator market, and the timing of Collins' stock sales, do not create a strong inference of scienter. Plaintiffs have not established that any individual Defendant was actually aware of information indicating that the Fidelis lead posed a significant risk of fracturing and such knowledge cannot be imputed to Medtronic. Moreover, the stock sales of the individual Defendants were not unusual or suspicious. Finally, the competing inference of Medtronic's good faith is more compelling, based on the record, than an inference of scienter. Therefore Plaintiffs' Section 10(b)/Rule 10b-5 claim must also be dismissed for failure to plead a strong inference of scienter.

II. Section 20(a) of the Exchange Act of 1934

Plaintiffs also allege that Defendants were "controlling persons" under Section 20(a) of the Exchange Act of 1934. (Compl. ¶¶ 193-96.) Section 20(a) imposes liability upon persons that control violators of, among other things, Section 10(b)/Rule 10b-5:

> Every person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable, unless the controlling person acted in good faith and did not directly or indirectly induce the act or acts constituting the violation or cause of action.

15 U.S.C. § 78t(a).

To establish a prima facie case of control-person liability, a plaintiff must allege "(1) a primary violation by a controlled person; (2) control of the primary violator by the defendant; and (3) that the controlling person was in some meaningful sense a culpable

participant in the primary violation." Boguslavsky v. Kaplan, 159 F.3d 715, 720 (2d Cir. 1998) (internal quotations and citation omitted). Defendants argue that Plaintiffs' claim under Section 10(b)/Rule 10b-5 is defective for failure to comply with the Reform Act, and therefore Plaintiffs have not sufficiently pleaded a violation of Section 20(a). The Court agrees. Because the Section 10(b) claim is not viable, the Court will grant the motion as to the claims under Section 20(a).

III. Leave to replead

Plaintiffs request leave to replead if any of their claims are determined to be deficient under the Reform Act. (Mem. in Opp'n at 51.) They argue that an amendment is appropriate as new facts have been revealed since the Complaint was filed. Specifically, Plaintiffs claim that new facts are contained in the Master Consolidated Complaint for Individuals in the Medtronic products liability lawsuit and an article published by Minnesota Public Radio. (Id.) Such facts include the assertion that (1) Medtronic offered Dr. Hauser funding to withhold the publication of the Hauser Study and (2) that Medtronic admitted its knowledge that several hospitals and clinics had suspended purchasing the Fidelis lead. (Id.)

The Federal Rules of Civil Procedure provide for liberality in granting leave to amend. Fed. R. Civ. P. 15(a)(2) ("The court should freely give leave when justice so requires.") However, a court may deny a request for leave to amend when the amendment would be futile or would cause undue delay or prejudice. Foman v. Davis, 371 U.S. 178, 182 (1962). Therefore, "parties should not be allowed to amend their

complaint without showing how the complaint could be amended to save the meritless claim." Wisdom v. First Midwest Bank, 167 F.3d 402, 409 (8th Cir. 1999).

In this case, the Court has already noted that allegations in the Master Consolidated Complaint for Individuals in the products liability lawsuit are insufficient to establish a strong inference of scienter.[24] Moreover, the Minnesota Public Radio article does not establish that any individual officer or director had knowledge of information regarding excessive Fidelis lead fracturing and therefore cannot establish scienter.[25] Thus, the addition of these allegations would not save the Complaint in this case. As Plaintiffs point to no additional information they would add to the Complaint if given the opportunity, the proposed amendment would be futile. Therefore, the Court denies Plaintiffs' request to replead.

CONCLUSION

The heightened pleading requirements of the Reform Act were passed to "curb frivolous, lawyer-driven litigation, while preserving investors' ability to recover on meritorious claims." Tellabs, 127 S. Ct. at 2509. Medtronic should not be required to endure burdensome and expensive discovery when Plaintiffs cannot allege securities fraud with particularity. See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 1966-67 (2007). Accordingly, because the Complaint does not comply with the requirements of the Reform Act, it must be dismissed.

[24] Plaintiffs do not argue that the allegations in the products-liability complaint pertain to the issue of materiality except for the allegation that Medtronic offered funding to Dr. Hauser to stop the publication of his study. This allegation has already been considered and deemed as insufficient to establish materiality.

[25] Such information is not alleged to be relevant to the issue of materiality.

Based on the foregoing, and all the files, records and proceedings herein **IT IS ORDERED** that Defendants' Motion to Dismiss (Doc. No. 57) is **GRANTED** and Plaintiffs' Amended Complaint (Doc. No. 46) is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: March 10, 2009

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge